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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,704	09/24/2001	William N. Drohan	CI-0006	4289

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	12

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/960,704	Applicant(s) Drohan et al.
	Examiner Randall Winston	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above, claim(s) *60-85* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-59* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1,5,6,10*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

The preliminary amendment filed on 3/25/03 has been entered.

Claims 1-85 are pending. Claims 1-59 will be examined on the merits. Claims 60-85 are withdrawn from consideration.

Election/Restriction

Applicants' election with traverse of Group I of claim 1 in Paper No.11 is acknowledged. The traversal is on the grounds that the applicant argues that specifically, claims 11-14, 2-23, 32-33, 44-58 and 78-84 depend directly from claim 1 and should be considered part of Group I. Furthermore, as claim 1 recites a method of irradiating a preparation of one or more enzymes, as do claims 2-85, such restriction is improper. Thus, it is respectfully submitted that the search and examination of the entire application could be made without serious burden.

Applicants' argument is not found persuasive because, as the Examiner explained in the Restriction Requirement (Paper No.7); Inventions' VII and VIII are unrelated to Group I because these two groups are drawn to a composition and Invention IX is unrelated to Group I because Invention IX is drawn to a different method from Group I. Thus, independent claim 1, newly amended dependent claims 2-6, 11-21, 23, 32, 22, 45, 47-59 and original dependent claims 7-10, 22, 24-31, 33-44, 46 are presented for examination on the merits (i.e. claims 1-59 are presented for examination on the merits).

The restriction requirement is still deemed proper and is therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 recite the phrase "reducing the temperature of said preparation." No objective criterion is provided in the specification or claim to apprise one of skill in the art of the meaning "reducing the temperature of said preparation." There is no definition of "reducing the temperature of said preparation" in the claims or specification to apprise one of skill in the art with an unambiguous meaning of the claimed invention-e.g., there is no temperature step proceding this step. Accordingly the metes and bounds of this phrase are not clearly delineated.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-58 of copending Application No. 09/942,938. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicants' two methods are drawn a similar method of sterilizing a preparation of one or more digestive enzymes (i.e.glycosidases) that is sensitive to radiation said method comprising: (I) applying to said preparation of one or more digestive enzymes (i.e glycosidases) at least one stabilizing process selected from the group consisting of (a) reducing the residual solvent content of said preparation of one or more digestive enzymes, (b) reducing the temperature of said preparation of one or more digestive enzymes, and (c) adding at least one stabilizer to said preparation of one or more digestive enzymes; and (ii)

irradiating said preparation of one or more digestive enzymes with a suitable radiation at an effective rate for a time effective to sterilize said preparation of one or more digestive enzymes, wherein said at least one stabilizing process (i.e or at least two stabilizing processes also claimed) and the rates of irradiation are together effective to protect said preparation of one or more digestive enzymes from said radiation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Kent (US 6,171, 549).

Applicant claims a method for sterilizing a preparation of one or more glycosidases that are sensitive to radiation, said method comprising irradiating said preparation of one or more

glycosidases with radiation for a time effective to sterilize said preparation of one or more glycosidases at a rate effective to sterilize said preparation of one or more glycosidases and to protect said preparation of one or more glycosidases from said radiation.

Kent anticipates the claimed invention by describing a method for sterilizing blood product comprising irradiating the blood product (please note, blood inherently contains one or more glycosidases as evidence by US 5585247, see, e.g., column 1 lines 32-34) with radiation for a time effective to sterilize said preparation of one or more glycosidases at a rate effective to sterilize said preparation of one or more glycosidases and to protect said preparation of one or more glycosidases from said radiation. Therefore, the reference is deemed to anticipate the claimed invention. (see, e.g., abstract, claims 1-19, especially claim 1)

Claims 1-5, 8-15, 33-36, 40- 41, 43, 46- 47, 49-50, 54 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Kent (US 6,171,549).

Applicant claims sterilizing a preparation of one or more glycosidases that are sensitive to radiation said method comprising: (i) applying to said preparation of one or more glycosidases wherein the preparation contains at least one biological contaminant or pathogen at least one stabilizing process selected from the group consisting of (a) reducing the residual solvent content of said preparation of one or more glycosidases (i.e. reduced by the method of claim 24), (b) reducing the temperature of said preparation of one or more glycosidases (?), and (c) adding at least one stabilizer to said preparation of one or more glycosidases; and (ii) irradiating said

preparation of one or more glycosidases with a suitable radiation at an effective rate for a time effective to sterilize said preparation of one or more glycosidases, wherein said at least one stabilizing process (i.e or at least two stabilizing processes claimed in claim 6) and the rates of irradiation are together effective to protect said preparation of one or more glycosidases from said radiation. Furthermore, the preparation of one or more glycosidases is maintained in a low oxygen atmosphere, atmosphere containing at least one noble gas, in a vacuum, and wherein at least one sensitizer is added to said preparation of one or more glycosidases prior to step of irradiating said preparation of one or more glycosidases.

Kent anticipates the claimed invention by describing a sterilizing a preparation of a blood product that is sensitive to radiation said method comprising: (i) applying to said preparation of a blood product wherein the preparation contains at least one biological contaminant or pathogen at least one stabilizing process selected from the group consisting of (a) reducing the residual solvent content (i.e. ethanol) of said preparation of a blood product (i.e. reduced by the method exampled in example 1), (b) reducing the temperature of said preparation of a blood product, and (c) adding at least one stabilizer (i.e. Citrate Phosphate Dextrose (CPD) to said preparation of a blood product; and (ii) irradiating said preparation of a blood product with a suitable radiation (i.e. gamma radiation) at an effective rate for a time effective to sterilize said preparation of a blood product, wherein said at least one stabilizing process and the rate of irradiation are together effective to protect said preparation of a blood product from said radiation. Therefore, the

reference is deemed to anticipate the claimed participation. (see, e.g., abstract, claims 1-19, especially claims 1, 5, 6, 9, and 17, and example 1)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kent (US 6,171,549).

The Kent reference is relied upon for the reasons discussed above. Kent does not expressly teach including within its method of sterilizing the preparation of a blood product the step of at least one sensitizer being added to said preparation of one or more glycosidases prior to step of irradiating said preparation of one or more glycosidases nor certain other claimed conventional working conditions.

However, Kent does beneficially teach sensitizer is a substance that selectively targets viral, mold, fungal, bacterial etc. (see, e.g., abstract, column 1 lines 54-64).

It would have been obvious to modify Kent's method of sterilizing the preparation of a blood product to include therein an additional step of adding at least one sensitizer thereto as

reasonably suggested by column 1 lines 54-64. Furthermore, based upon the overall beneficial teachings provided by Kent, the result-effective adjustment of other claimed conventional working conditions therein (e.g., maintaining in a low oxygen atmosphere, using an atmosphere containing at least one noble gas, utilizing two commonly employed stabilizing processes, the rates and times of irradiation, different types of irradiation, different modes of conducting such as below or above ambient temperature, below freezing point, below the eutectic point), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Moreover, the art-recognizes functional or mechanical equivalency of a claimed compound/element with that of the prior art compound/element provides a *prima facie* case of obviousness for the skilled artisan to interchangeably substitute one equivalent for the other (see, e.g. MPEP 2144.06) within method of sterilizing a blood product (e.g. residual solvent substitution, stabilizer substitution and radiation substitution). In addition, please note the selection of any order of performing process steps (i.e. utilizing two commonly employed stabilizing processes) is *prima facie* obvious in the absence of new or unexpected results. (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330-CCPA 1946) MPEP 2144.04).

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is (703) 305-0404. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

row

CHRISTOPHER R. TATE
PRIMARY EXAMINER